Pharmacovigilance in Australia

Rohan Hammet

Australia

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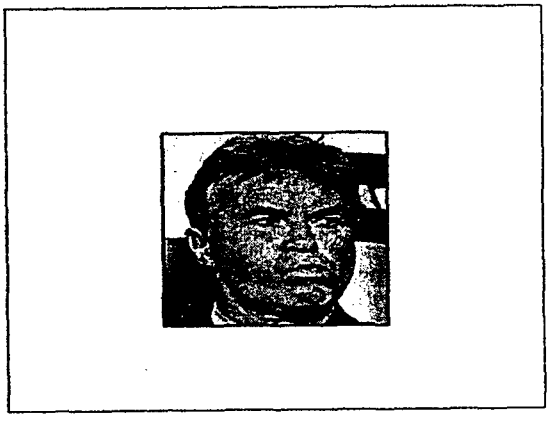
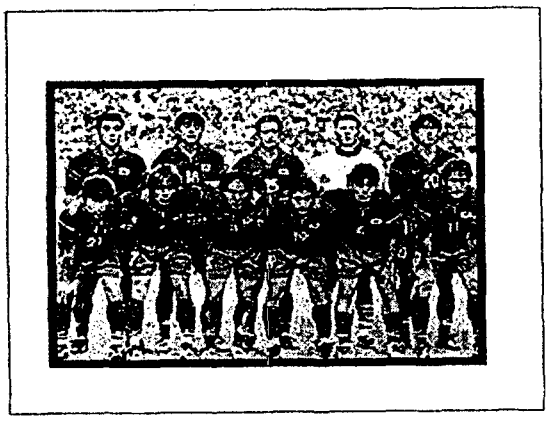
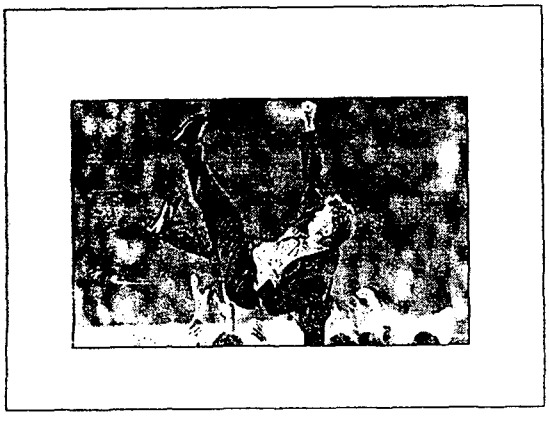
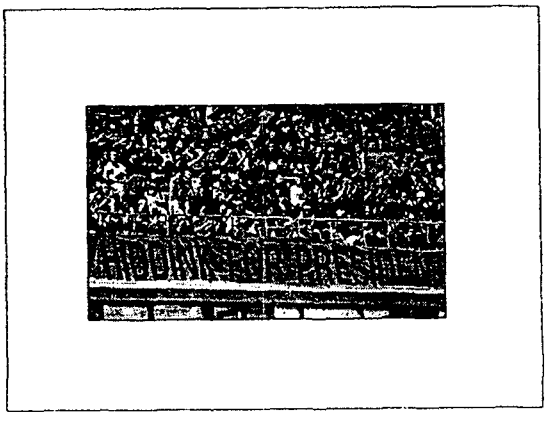
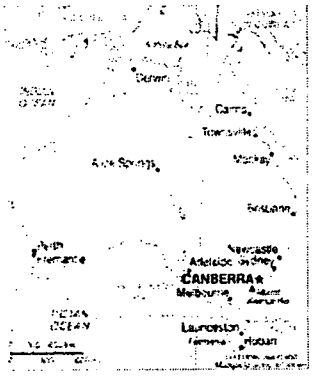
Principal Medical Adviser, Therapeutic Goods Administration

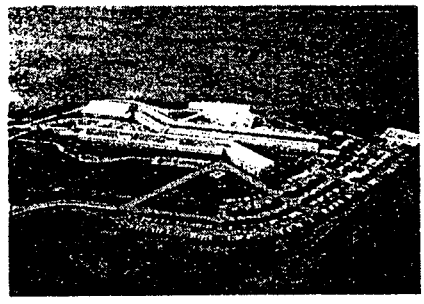












Pharmacovigilance

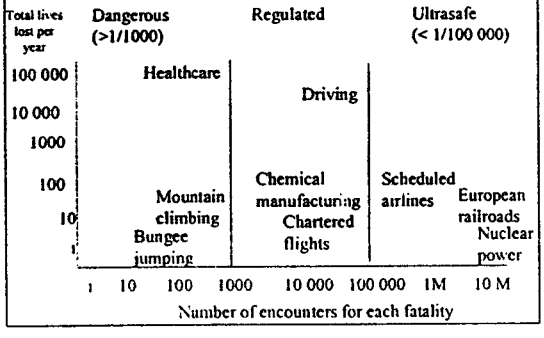
- **The past**
- **The present**
- **The future**

Australian Health Statistics

- since 1920, progressive reduction in mortality from 7 of 10 major causes of death
- 30 years added to life expectancy
- since 1985/86 - 30% increase in health services for an extra 1% of G.D.P.
- productivity savings (Anaesthesia & Surgery) $4 billion/ year over 20 years
- in line with most advanced, modern health systems in-hospital adverse event rate approx. 10%

How hazardous is healthcare?

(Leape)



Medicines regulation by TGA

- TGA regulates prescription, over-the-counter, and complementary medicines (including vitamins, mineral, and herbal)
- current product numbers:
  - prescription 6655
  - OTC 3756
  - complementary 16515

TGA also regulates ...

- vaccines and biologicals (as medicines)
- medical devices
- blood, tissues, blood products
- industrial chemicals
- gene technology
- advertising
- not food

Pharmacovigilance at TGA

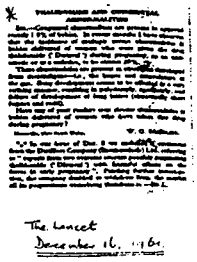
- premarket (DSEB)
- postmarket (ADRU/DSEB)
- sampling
- recalls
- surveillance

Premarket activities

- submissions received 2004-05
  - prescription medicines 1324
  - non-prescription medicines 5182
  - medical devices 9124

Pharmacovigilance – The Past

•1961 thalidomide embryopathy



The Lancet
December 16, 1961

Pharmacovigilance – The Past

- 1961: thalidomide
- 1963: ADEC established
- 1964: ADR reports sought
- 1968: WHO drug monitoring
- 1970: ADRAC established
- 1971: ADRS database initiated

Pharmacovigilance – The Present

Adverse Drug Reactions Unit (ADRU)

- major activities:
  - maintenance of reporting scheme
  - secretariat for ADRAC
- staffing:
  - 4 medical
  - 3 scientific
  - 6 clerical

ADR reporting in Australia

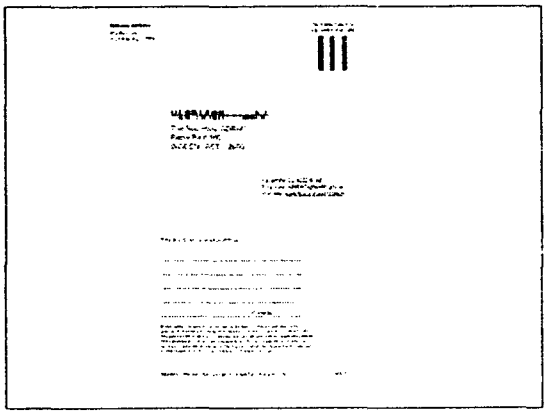
- 213,000 reports in database
- top six nations for volume of reports
- top few for reports per capita

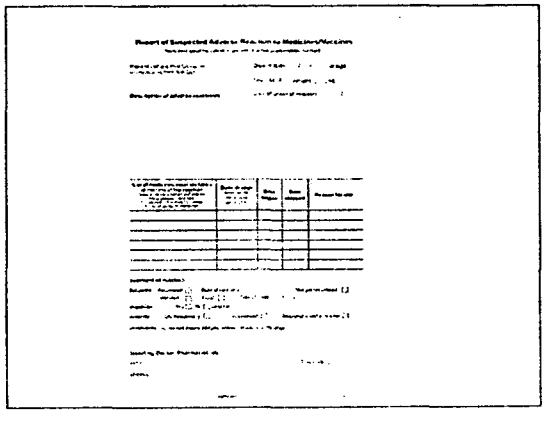
ADR reporting - 2

- single scheme covers prescription, OTC, and complementary medicines
- reports accepted from doctors, hospitals, sponsors, other health professionals, and consumers
- around 10,000 reports annually
- all reports reviewed by medical or scientific staff at time of receipt

ADR reporting - 3

- of 10,000 reports annually:
  - ~94% involve prescription medicines
  - ~3% each OTC and complementary medicines
  - 80-90% from GPs, hospitals, industry, and State Health Departments
  - ~3% from consumers over recent years

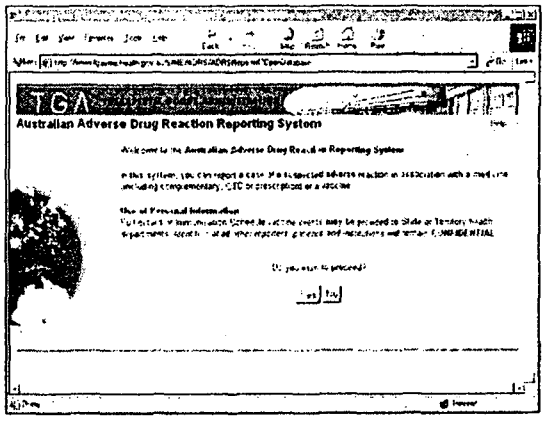


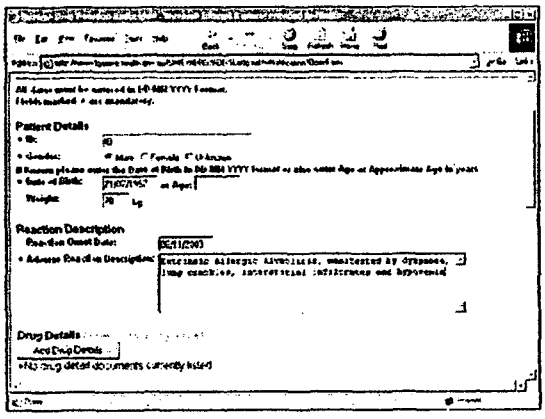


Electronic reporting

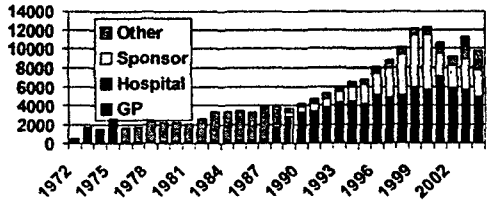
Commenced January 2003

- 2003: 484 electronic reports (4.1% annual total)
- 2004: 506 electronic reports (5.1% annual total)





Spontaneous reporting, 1972-2004



ADRAC

- independent advisory committee
- formed 1970
- 8 members (medical specialists)
- 8 meetings per year
- 6 Bulletins published per year:
  - circulation 60,000
  - http://www.tga.gov.au/adr/aadrb.htm

Other ADRU activities

- review medical literature, other regulators, and media
- targeted PSUR review
- enquiries from database (>3000/year from industry, drug information services, academics, consumers – not FOI)
- parliamentary and ministerial responsibilities

ADRU international activities

- participation in WHO network
- videoconference every 2 months:
  - FDA, Health Canada, Medsafe NZ
- teleconference every 2 months:
  - NZ, Singapore
- WHO annual National Centres meeting
- WHO training course every 2 years

Pharmacovigilance guideline

- describes responsibilities of sponsors in reporting adverse reactions to TGA
- currently applies only to prescription medicines; under development for OTC and complementary medicines
- http://www.tga.gov.au/adr/pharmaco.pdf

Adverse Medicines Event Line

- facility for consumers to report or seek advice on problems with medicines
- hospital-based; government-funded
- summary of calls:
  - 2781 calls received
  - 726 adverse events
  - 552 reports sent to TGA/ADRAC

Other TGA postmarket activities, 2004-05

• recalls	
– prescription medicines	27
– other medicines	54
• surveillance activities	
– breaches reported	421
– warnings issued	161
– criminal charges laid	106

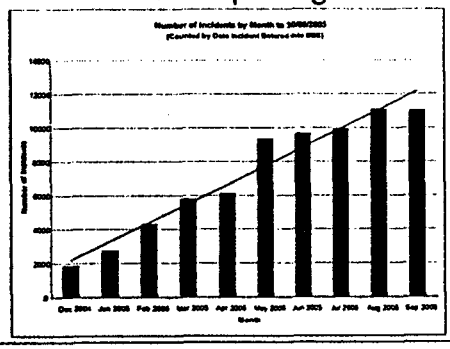
TGA labs postmarket, 2004-05

- problems and complaints:
  - 607 samples tested
  - 178 failed
- targeted testing:
  - 399 samples tested
  - 60 failed

Pharmacovigilance

The Future

Real reporting



Data Linking Australian Health Databases

National Prescription (PBS) databases. -Pharmacy reimbursement; -Authority prescriptions. (incomplete capture). (20 million)

National Medical Services & Procedures (Medicare) reimbursement database. (20 million)

Eight State & Territory Public Hospital Records Databases.

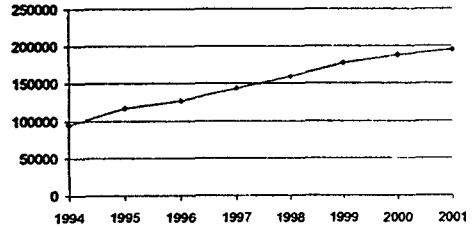
Studies using PBS database

- Dispensing/co-dispensing "gastrointestinal drugs" in patients taking alendronate and calcitriol
- Co-prescribing with cisapride
- Demographics of isotretinoin prescribing
- Triple whammy

Studies using PBS database

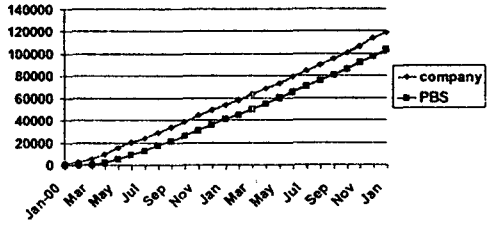
- Incidence of pancytopenia in patients taking leflunomide with or without methotrexate
- presented as poster at ISPE, Aug 2004
- 14791 first dispensings of leflunomide in 31 months

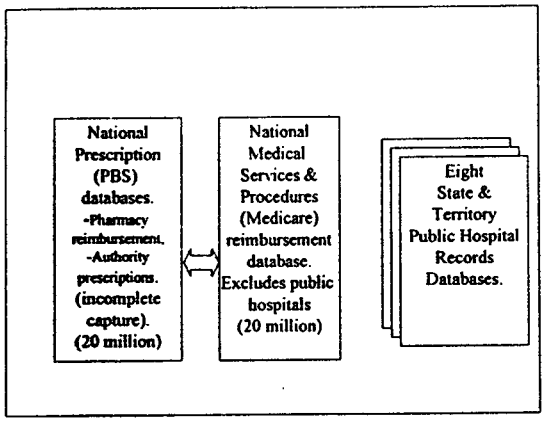
Isotretinoin dispensings

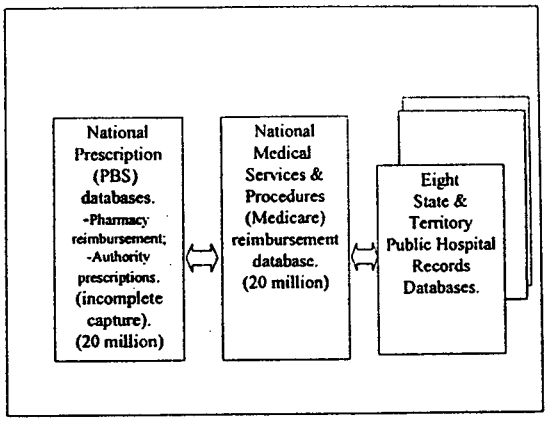


Leflunomide dispensing - 20mg

Grateful acknowledgment to Aventis Pharma Australia Pty Limited







For the future

- statistical tools to predict population effects e.g cusum analysis
- electronic reporting by sponsors
- external access to database
- broaden pharmacovigilance guidelines
- trans-Tasman joint agency